



**Testimony
Before the Subcommittee on Criminal Justice,
Drug Policy and Human Resources
Committee on Government Reform
United States House of Representatives**

**The Role of the HHS Office of Research
Integrity in Investigating Research
Misconduct**

Statement of

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Chairman Souder and Distinguished Members of the Subcommittee, I appreciate the opportunity to speak to you today about research misconduct and the work of the Office of Research Integrity (ORI) in the Department of Health and Human Services (HHS).

ORI is charged with overseeing allegations of research misconduct in biomedical and behavioral research supported by U.S. Public Health Service (PHS) funds. ORI has over 10 years of experience in reviewing misconduct allegations and making findings of research misconduct. PHS-supported research institutions and ORI make findings of research misconduct when evidence demonstrates that fabrication, falsification, or plagiarism has occurred in PHS-funded research. ORI has made more than 160 findings of misconduct since 1992 and has reviewed hundreds of additional allegations that did not result in misconduct findings. In May 2005, HHS published a new, more comprehensive regulation governing research misconduct investigations entitled, "Public Health Service Policies on Research Misconduct" ("the HHS regulation"), codified at 42 CFR part 93, which may be found on the ORI website at: http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf. This new regulation replaces the previous regulation from 1989 (42 CFR part 50 subpart A) for dealing with and reporting research misconduct.

ORI is aware of the controversy regarding Dr. Woo Suk Hwang's human stem cell research project at Seoul National University and the findings of research fraud by the Seoul National University Investigation Committee. However, based on the information currently available to ORI, ORI has no jurisdiction in this matter, since the research was not supported by PHS funds, and ORI does not have jurisdiction over non-PHS-supported research.

Had the actions been under the purview of HHS, ORI has a staff of scientists and additional consultants who have developed extensive knowledge and expertise in overseeing and assessing allegations of research misconduct, primarily through evaluating investigations conducted by PHS-funded research institutions. By law, direct investigations are usually initiated by the research institutions that receive allegations of research misconduct. These allegations are generally made by members of the grantee institution who are part of the particular laboratory or department conducting the research. One or more members of the team may suspect misconduct and then report it to the grantee institution directly. Sometimes the investigator suspecting fraud will report to ORI, and then ORI will refer it to the appropriate grantee institution for review. Grantee institutions are required by the HHS regulation to report allegations to ORI when they reach the formal investigation stage of the process or when admissions are made by the accused scientist.

In conducting the investigation, the institution must promptly secure the research records and other relevant documents in order to have a sound basis to identify and evaluate any evidence of research misconduct. When an institution has completed its investigation, it must submit a written investigation report to ORI. ORI will then engage in a thorough oversight review of the report and, depending on the quality and thoroughness of the investigation, may accept the institution's report and find either misconduct or no misconduct based on that report.

If ORI believes further investigation is required, ORI may request and review the grantee institution's investigation record, including the research data, copies of interviews or tapes, and other relevant documents. When the analysis is completed, ORI may find no misconduct and close the case, or propose PHS findings of research misconduct. ORI findings of no misconduct, as well as open cases that are under review, are considered confidential, and ORI does not discuss these cases publicly. When HHS makes a finding of misconduct, however, it formally announces the finding which is then published in the Federal Register and summarized on the ORI website and in our newsletter, and the finding is listed in the NIH Guide for Grants and Contracts.

HHS takes findings of research misconduct seriously and takes appropriate action. Findings of research misconduct typically result in remedial HHS administrative actions that may include debarment or suspension from PHS-supported research, supervision or certification of the responsible researcher's future work, and prohibition from PHS advisory committee service. ORI also strives to correct the research record that may have been corrupted by fraudulent studies, requesting that scientific journals publish retractions or corrections of papers containing falsified or fabricated findings. In those research misconduct cases that result in criminal fraud charges and civil proceedings of false claims, ORI works collaboratively with the Department of Justice and other Federal law enforcement agencies, including the HHS Office of the Inspector General. Accused scientists who wish to contest findings of research misconduct are offered an administrative hearing by HHS.

In order to promote research integrity and responsible research practices, ORI also has an active education program, collaborates with scientific societies and institutions, and provides resources to institutions to develop their own educational products.

ORI believes that its educational programs and collaborations with the research community can help prevent research misconduct. For example, ORI has a collaboration with the Association of American Medical Colleges to fund scientific and academic societies to hold workshops and conferences on research integrity issues or to develop guidelines or educational programs describing appropriate normative standards for conducting and reporting research. ORI also has a collaboration with the Council of Graduate Schools to fund pilot projects at 10 institutions to provide formal training to graduate students in the responsible conduct of research (RCR). ORI has also published a booklet on RCR that has been translated into Chinese and Japanese. Finally, ORI has an active program of evaluation and research studies, partly in collaboration with the National Institutes of Health within HHS, to determine what scientific practices are working well and to learn what practices can be improved.

Although any individual case of research misconduct can have serious consequences for biomedical research, it is ORI's experience that the great majority of scientists are dedicated to conducting research in a responsible and professional manner and are committed to producing research results that will benefit all Americans and health care consumers around the world.

Thank you for the opportunity to discuss ORI's work with you. I would be pleased to answer any questions you may have.